



Attachment C: Summary of Safety and Effectiveness

FEB 13 1997

[510(k) Summary]

K963045

SYNTHES (U.S.A.)  
1690 Russell Road  
Paoli, PA 19301

(610) 647-9800  
Angela Silvestri

**Device:**

SYNTHES (U.S.A.) Universal Sacral System compared to the Universal Spinal Hook, Rod, and Pedicle/Sacral Screw Fixation System Side Opening Screw and Transverse Bar, and the Sofamor Danek Texas Scottish Rite Hospital (TSRH) Pedicle Spinal Screw System Variable Angle Screw, and the Titanium TSRH Spinal System (Screws) Variable Angle Screw.

**When used as a posterior pedicle screw fixation system, the SYNTHES Universal Sacral System is intended for patients with severe spondylolisthesis (Grades 3 and 4) of the fifth lumbar-first sacral (L5-S1) vertebral joint; who are receiving fusions using autogenous bone graft only; who are having the device fixed or attached to the lumbar and sacral spine; and who are having the device removed after the development of a solid fusion.**

**When used as a posterior, non-pedicle screw fixation system, the SYNTHES Universal Sacral System is also intended for scoliotic, lordotic, or kyphotic deformities (such as scoliosis, Schuermann's disease); degenerative disk disease (back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies), and fractures of the posterior thoracolumbar spine (levels T8-S2).**

The overall levels of fixation for the Universal Sacral System as a whole are T8-S2. The levels of pedicle screw fixation are L3-S2.

The SYNTHES (U.S.A.) Universal Sacral System allows a screw to be connected to the rod through a wide array of screw/rod angles. It consists of a sacral screw assembly with a sacral collar a nut, and a rod. The assembly consists of a sacral screw, a rod/screw connector, and a locking ring. This system is to be used with the SYNTHES (U.S.A.) Universal Spinal Hook, Rod, and Pedicle/Sacral Screw Fixation System.

The SYNTHES (U.S.A.) Universal Sacral System is manufactured from titanium alloy, which conforms to ASTM Standard F1295-92, and 316L stainless steel which conforms to ASTM Standard F138-86.

The SYNTHES (U.S.A.) Universal Spinal Hook, Rod and Pedicle/Sacral Screw Fixation System Side Opening Screw, Transverse Bar and the Texas Scottish Rite Hospital (TSRH) Variable Angle Screw are indicated for the same intended use as the SYNTHES (U.S.A.) Universal Sacral System.

The SYNTHES (U.S.A.) Universal Spinal Hook, Rod and Pedicle/Sacral Screw Fixation System is manufactured from titanium alloy, which conforms to ASTM Standard F1295-92, and 316L stainless steel, which conforms to ASTM Standard F138-86.



The Texas Scottish Rite Hospital Variable Angle Screw is manufactured from certified Implant Grade stainless steel and a titanium alloy (Ti-6Al-4V). These systems are similar in component dimensions and sizes to the *SYNTHES* (U.S.A.) Universal Sacral System.

The Synthes Universal Sacral System is provided non-sterile; moist heat sterilization is recommended.

Based on the above, the *SYNTHES* (U.S.A) Universal Sacral System is substantially equivalent to the Universal Spinal Hook, Rod and Pedicle/Sacral Screw Fixation System Side Opening Screw and the Transverse Bar, and the Texas Scottish Rite Hospital (TSRH) Variable Angle Screw.